

| | | |
|-------------------------------|---------------------|---------------|
| Notice of Allowability | Application No. | Applicant(s) |
| | 10/602,469 | STATON ET AL. |
| | Examiner | Art Unit |
| | Albert J. Gagliardi | 2878 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to submissions of 23 June 2003.
2. The allowed claim(s) is/are 21-39 and 50.
3. The drawings filed on 23 June 2003 are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

5. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) The translation of the foreign language provisional application has been received.
6. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No. _____.
 - (b) including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

| | |
|--|--|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9 <input type="checkbox"/> Other |
|--|--|

Albert J. Gagliardi
 Primary Examiner
 Art Unit: 2878

EXAMINER'S COMMENT AND STATEMENT OF REASONS FOR ALLOWANCE

Comment on Submissions

1. The preliminary amendment filed 23 June 2003 has been entered.

Information Disclosure Statement

2. The examiner has considered information considered by the Office in parent application 09/892,209 when examining this continuing application, and the application file reflects that fact. A list of the information need not be submitted in the continuing application unless the applicant desires the information to be printed on the patent. See MPEP § 609.

Allowable Subject Matter

3. Claims 21-39 and 50 are allowed.
4. The following is an examiner's statement of reasons for allowance:

Regarding independent claim 20, the prior art does not disclose or fairly suggest a method of calibrating a scanning system used for scanning an array of biomolecules that has an excitation light source, an optics portion, and a detection portion, as specifically claimed including at least the steps of initially calibrating the detection portion with a reference light level and producing an initial output stored for reference; and subsequently calibrating the detection portion with a calibration apparatus that produces light at the reference level.

The examiner notes that while systems for scanning microrays as well known in the art, such prior art systems seem unconcerned with methods of calibration (Perov *et al.* -- US 6,329,661, for example), or utilize an alternative calibration means which relies on the use of a calibration standard (Dietz *et al.* -- US 5,689,110), a calibration assay sample (Mabile *et al.* -- US 6,352,672, for example), a reference sample (Noble -- US 6,471,916 and Giebel *et al.* -- US 6,316,774, for example) or samples (Curry *et al.* -- US 4,295,199), or a control reference

sample (Shalon *et al.* US 2003/0012695, for example), instead of a reference light level provided by a calibration portion.

The examiner further notes that while it is well known to utilize a reference light level for detector calibration in other types of radiation detection systems such as gamma cameras (Taravelle *et al.* US 5,373,161, for example) and optical viewing systems (Shimizu -- US 5,325,171, for example), as well as in fluorescent detection systems (Ballard *et al.* -- US 5,548,115, and Nestor *et al.* US 4,900,933), there is no suggestion in the prior art, absent hindsight reasoning to modify the known microarray scanning systems to substitute and/or include an additional calibration portion providing a reference light level. The examiner also notes that calibration utilizing a reference source is not considered as a functionally equivalent calibration means since such calibration does not account for changes in either the excitation source or the calibration apparatus.

The remaining claims are allowed on the basis of their dependency.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Albert J. Gagliardi whose telephone number is (703) 305-0417

Application/Control Number: 10/602,469

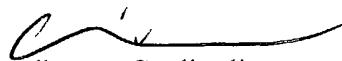
Page 4

Art Unit: 2878

(after January 20 2004 the new number will be (571) 272-2436. The examiner can normally be reached on Monday thru Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David P. Porta can be reached on (703) 308-4852. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9318.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



Albert J. Gagliardi
Primary Examiner
Art Unit 2878

AJG